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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,269	09/23/1999	RANDALL S. ALBERTE	CEA-004.01	9298
25181	7590	05/05/2004	EXAMINER	
FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			YAMNITZKY, MARIE ROSE	
			ART UNIT	PAPER NUMBER
			1774	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

Office Action Summary

Application No.

09/405,269

Applicant(s)

ALBERTE ET AL.

Examiner

Marie R. Yamnitzky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63, 66-74 and 89-91 is/are pending in the application.
- 4a) Of the above claim(s) 27, 28 and 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26, 29-33, 38-63, 66-74 and 89-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. This Office action is in response to applicant's amendment received January 30, 2004, which amends the specification and claims 1, 5, 29, 31, 39, 42-45, 48, 49, 52-54, 56-58, 61, 62 and 67, and cancels claim 64.

Claims 1-63, 66-74 and 89-91 are pending.

2. In applicant's amendment, the status identifier for claim 29 is "previously presented" but the examiner notes that the phrase "over a defined period of time" in line 3 was not part of the prior version of claim 29.

3. In applicant's proposed amendment to the specification, the page, paragraph and line numbers used to identify the portions to be amended do not correspond to the text of the substitute specification filed May 14, 2001. For example, the second full paragraph on page 9 of the specification reads "In a health related environment...rapidly become fatal." As another example, the first line on page 22 only contains a formula. The amendment to the specification filed January 30, 2004 cannot be entered as presented because it introduces errors and confusion into the specification.

The examiner has marked a copy of the amendment to the specification as "DO NOT ENTER". The present application has been converted from a paper file to an electronic file. The examiner suggests that replacement pages (rather than paragraphs) be submitted for pages 9-12, 22 and 24 showing the correct text in case the examiner's instructions are not correctly noted in the electronic file.

One of applicant's proposed changes to the specification is the deletion of the first paragraph on page 10. The indicated paragraph actually appears on page 11. The examiner notes that deletion of the first full paragraph on page 11 would introduce new matter because the deletion has the effect of altering the meaning of "alkyl" and "lower alkyl" as used by applicant. Deletion of this paragraph would also remove antecedent basis in the specification for at least a portion of the definition of Z as set forth in independent claims 1 and 39. If applicant is of the position that the deletion does not introduce new matter, applicant is required to explain on the record why the deletion does not introduce new matter.

4. Rejections of claim 64 as set forth in the Office action mailed August 27, 2003 are rendered moot by the cancellation of claim 64.

Applicant's amendment overcomes the rejection of claims 1-5, 7-13, 16, 17, 19-22, 25, 26, 29-33, 38-43, 45-51, 54, 55, 57-60, 63, 66-74 and 89-91 under 35 U.S.C. 112, 1st paragraph (for failing to comply with the written description requirement), as set forth in August 27th action.

Applicant's amendment overcomes the rejection of claims 39-42, 44-49, 52-54, 56-58, 61-63, 66, 68-73 and 89-91 under 35 U.S.C. 102(b) as anticipated by The Merck Index, Tenth Ed. (1983), pp. 876-877.

5. The claims remain subject to an election of species. In Paper No. 11, applicant elected the species of a compound of general structure 1, applied to the surface of a medical device,

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wherein X represents -OH, Y represents O and Z represents an optionally substituted aryl.

Claims 1-26, 29-33, 38-64, 66-74 and 89-91 continue to read on the elected species. (Claims dependent from claim 39 which further limit the article are all considered to read on the elected species since, for claims 39 and dependents, the article pertains to the intended use of the claimed coating.)

Claims 27, 28 and 34-37 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

6. The disclosure stands objected to because of the informalities noted in Paper No. 18 (action mailed August 27, 2003).

7. Claims 31 and 67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 31 and 67 have been amended to include a range for “% by weight”. The original claims set forth a range for “%” without specifying whether the percent was a percent by weight, volume or moles, and without specifying whether the percent was measured relative to the biofilm resistant surface or the system as a whole. In amending the claims to recite “% by

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weight”, applicant states that percent by weight is conventionally used to describe solids.

However, the claims are not limited to solids. It is not clear that the percents as set forth in the application as originally filed necessarily referred to percents by weight.

8. Claims 1-26, 29-33, 38-63, 66-74 and 89-91 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record in Paper No. 18.

9. Claims 1-26, 29-33, 38-63, 66-74 and 89-91 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of Z is not clear because Z as further defined in some of the present pending claims is not consistent with Z as defined in the present independent claims. Several dependent claims allow Z to represent optionally substituted heteroalkylphenyl. It is not clear how heteroalkylphenyl or substituted heteroalkylphenyl fit within the definition of Z as set forth in the dependent claims. Claims 5, 43 and several other dependent claims also allow Z to be optionally substituted alkylphenyl, arylphenyl or heteroarylphenyl. While it is clear that alkylphenyl, arylphenyl or heteroarylphenyl are within the scope of Z as defined in the independent claims, it is not clear how substituted alkylphenyl, substituted arylphenyl and substituted heteroarylphenyl are within the scope of Z as defined in the independent claims. Claims 6, 44 and several other dependent claims allow Z to represent 4-(1-methyl-1-phenylethyl)phenyl but it is not clear how this possibility meets the limitations of Z as set forth in the independent claims.

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Claim 29 is rendered indefinite by the recitation of "over a defined period of time" with no limitation on the defined period of time.

Claim 31: It is not clear if the % by weight of the compound is measured relative to the weight of the biofilm resistant surface, or relative to the claimed system as a whole.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 39-63, 66-74 and 89-91 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34-58 and 65-78 of copending Application No. 09/405,299 for reasons of record in Paper No. 18.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Applicant is reminded that should claim 68 be found allowable, claim 69 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

Applicant's arguments filed January 30, 2004 have been fully considered but they are not persuasive with respect to the objection and rejections maintained in this Office action.

With respect to the objection to the disclosure, applicant's amendment to the specification could not be entered as presented and therefore no changes have been made to the specification.

Several issues are raised in the rejection under 35 U.S.C. 112, 2nd paragraph. With respect to the issue of the scope of "Z" and the possibility of Z being an optionally substituted heteroalkylphenyl as set forth in some dependent claims, applicant has deleted "heteroalkylphenyl" from the definition of Z in dependent claims 5 and 43 but optionally substituted heteroalkylphenyl remains a possibility for Z as defined in various other dependent claims.

With respect to the issue of the scope of "Z" and the possibility of Z being a substituted alkylphenyl, substituted arylphenyl or substituted heteroarylphenyl, and the related issue of Z representing 4-(1-methyl-1-phenylethyl)phenyl, the independent claims set forth a Markush group for the optional substituent. If each member of the Markush group may be further substituted with unlimited substituents, then substituted alkylphenyl, substituted arylphenyl, substituted heteroarylphenyl and 4-(1-methyl-1-phenylethyl)phenyl as set forth in some of the dependent claims are within the scope of Z as defined in the independent claims. For example, 4-(1-methyl-1-phenylethyl)phenyl is a substituted aryl group wherein the substituent is an alkaryl-substituted alkyl group or an alkyl-substituted aralkyl group, but such substituents are not explicitly recited as part of the Markush group in the independent claims. It is not clear that each

member of the Markush group may be further substituted with unlimited substituents. The independent claims do not explicitly allow the members of the Markush group of substituents to be further substituted, and some members of the Markush group are redundant if further substitution is allowed. For example, "aralkyl" and "trifluoromethyl" are examples of substituted alkyl groups. Why recite "aralkyl" and "trifluoromethyl" separately from "alkyl" in the Markush group if "alkyl" encompasses all substituted alkyl groups?

With respect to the rejection under 35 U.S.C. 112, 1st paragraph (scope of enablement), applicant argues that the experiments in the specification demonstrate that the $-YS(O)_2X$ moiety imparts the anti-fouling properties to the system or coating and that compounds having this moiety are effective at preventing biofouling with a wide variety of Z moieties usable for the compound. The examples set forth in the specification utilize four different compounds, three of which are within the scope of the compound of general structure 1 as defined in present claim 1 and one of which is within the scope of the compound of general structure 1 as defined in present claim 39. The only feature in common between the four compounds utilized in the examples and all the compounds encompassed by structure 1 as defined in claim 1 or claim 39 is the $-S(O)_2-$ moiety. The claims cover compounds in which the two monovalent radicals ($-Y-Z$ and $-X$) can be quite chemically different than those of the disclosed species.

With respect to the terms "coating" and "system", the examiner acknowledges that it is not necessary for, nor would it be reasonable to expect, applicant to prepare an actual example for every possible coating and every possible system encompassed by the present claims. However, it is the examiner's position that the examples set forth in the specification are not

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representative of the entire genus of coatings and systems encompassed by the rejected claims.

The rejection as set forth in Paper No. 18 discusses the breadth of the claims and the reasons why the examiner considers the specification to provide enablement for much less than the entire scope of the claims. Applicant's arguments do not persuade the examiner to the contrary.

With respect to the provisional obviousness-type double patenting rejection, the rejection cannot be held in abeyance. However, at such time as all other grounds of rejection are overcome or withdrawn, the examiner will consider the propriety of withdrawing or maintaining the rejection in accordance with MPEP 822.01.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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14. Any inquiry concerning this communication should be directed to Marie R. Yamnitzky at telephone number (571) 272-1531. The examiner works a flexible schedule but can generally be reached at this number from 6:30 a.m. to 4:00 p.m. Monday, Tuesday, Thursday and Friday, and every other Wednesday from 6:30 a.m. to 3:00 p.m.

The current fax number for Art Unit 1774 is (703) 872-9306 for all official faxes.
(Unofficial faxes to be sent directly to examiner Yamnitzky can be sent to (571) 273-1531.)

MRY
May 03, 2004



MARIE YAMNITZKY
PRIMARY EXAMINER

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